



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,730	03/03/2004	Makoto Ozeki	1422-0625P	2621
2292 7590 03/14/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER CLAYTOR, DEIRDRE RENEE				
ART UNIT 1617		PAPER NUMBER		
NOTIFICATION DATE 03/14/2008		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

# Office Action Summary

**Application No.**

10/790,730

**Applicant(s)**

OZEKI ET AL.

**Examiner**

Renee Claytor

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants response filed on 12/18/2007 has been fully considered. Claims 4-12 are presently under examination

Applicants have amended claims 4-5 to include the claim limitation that the "...said mood disorders are distinct from mood disorders associated with menstruation". Applicants argue that the Ueda reference used in the 35 USC 102 and 103 rejections is directed to a theanine-containing composition for suppressing and ameliorating various symptoms accompanying diminished homeostasis, obesity suppression, suppression of anxiogenic symptoms and premenstrual syndrome, amelioration of sensitivity to cold, menopausal disorders, sleep disorders and autonomic imbalance. Applicants argue that the above listed disorders have nothing to do with mood disorders as recited in the claimed invention and further the mood disorders are distinct from mood disorders associated with menstruation as now claimed.

The newly added claim limitation of excluding mood disorders associated with menstruation has been fully considered. While this limitation is now recognized, the rejection also referred to the list of symptoms in Col. 5 which include such symptoms such as anxiety. Considering that mood disorder is being construed very broadly as anything that affects the mood, it is considered that symptoms such as anxiety meet this limitation because anxiety is known to affect the mood in an individual. Accordingly, the 35 USC 102 and 103 rejections over Ueda are being maintained and modified due to Applicants amendments.

Art Unit: 1617

Applicants filing and approval of a Terminal Disclaimer over Application 10/343,931 is sufficient to overcome the Double Patenting rejection and it is hereby withdrawn.

***Claim Rejections – 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 4 and 6 rejected under 35 U.S.C. 102(e) as being anticipated by Ueda et al. (U.S. Patent 6,831,103).

Ueda et al. teaches the administration of a theanine-containing composition that is capable of ameliorating symptoms such as anxiogenic symptoms that include those symptoms due to an unidentified cause (Col. 4, lines 41-61 and Test Example 3). Further, diminished homeostasis is a symptom treated with theanine and further symptoms of diminished homeostasis include spiritlessness, aggressiveness, faintheartedness, maudlinness and psychological lift that all meet the broad limitation of mood disorder because these are symptoms associated with mood (see claim 1). Ueda et al. further teach that theanine may be contained in different types of food or beverages (Col. 6, lines 8-67 – Col. 7, lines 1-17).

***Claim Rejections – 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 7-12 rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. (U.S. Patent 6,831,103) as applied to claims 4 and 6 above in view of Hamilton (J Neurol Neurosurg Psychiat, 1960, 23, 56).

Ueda et al. teach a method for ameliorating different types of mood, such as a anxiety and diminished homeostasis (meeting the limitations of claims 5, 8 and 12), with a food or beverage containing theanine.

Ueda et al. do not specifically teach that the mood is assessed by the Hamilton scale or all of the different types of mood listed in claims 9-11.

Hamilton teaches a rating scale for measuring symptoms of mental disorder, including the symptoms such as depressed mood, feelings of guilt, suicide, retardation:psychomotor and diminished insight (see whole document).

Accordingly, it would be obvious to a person of ordinary skill in the art at the time of the invention that the Hamilton scale would be an effective assessment of symptoms of mood disorders because of the teachings of Ueda et al. that theanine containing compositions are effective in treating various types of mood, particularly those associated with anxiety and diminished homeostasis. One would be motivated to use the Hamilton scale because it is a scale commonly used to assess various mood

disorders, including depressed states. Therefore, the other factors in the scale would also be measured.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617